

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

**FOREST LABORATORIES, LLC,
FOREST LABORATORIES HOLDINGS,
LTD., and ALLERGAN
PHARMACEUTICALS
INTERNATIONAL LTD.,**

Plaintiffs,

v.

**SIGMAPHARM LABORATORIES, LLC,
*et al.,***

Defendants.

**Civ. No. 14-1119- MSG
CONSOLIDATED**

MEMORANDUM OPINION

GOLDBERG, J.

August 6, 2019

The current controversy in this ongoing Hatch-Waxman case involves a motion by defendant Sigmapharm Laboratories, LLC (“Sigmapharm”) to vacate a finding of infringement pursuant to Fed. R. Civ. P. 60(b) based on a post-trial amendment to its Abbreviated New Drug Applications (“ANDA”). (D.I. 411). Plaintiffs Forest Laboratories LLC, Forest Laboratories Holdings, Ltd., and Allergan Pharmaceuticals International Ltd. (collectively, “Forest”) oppose Sigmapharm’s motion and have filed a cross motion to enter final judgment. (D.I. 413). For the reasons stated below, Sigmapharm’s motion will be denied and Forest’s motion will be denied without prejudice.

BACKGROUND

A. The Consolidated Case

In September 2014, Forest initiated several patent infringement actions against companies that had filed ANDAs under the Hatch-Waxman Act, 21 U.S.C. § 355, seeking FDA approval to market generic versions of Saphris[®], an asenapine maleate tablet. Among other issues raised, Forest asserted that the defendants infringed claim 1 of U.S. Patent No. 5,763,476 (“the ’476 patent”), which requires that the pharmaceutical composition “disintegrate[] within 30 seconds in water at 37° C.” (D.I. 409 at 5, 7). These actions were consolidated and originally overseen by the Honorable Sue L. Robinson, now retired. (*Id.* at 3).

B. Specifications 1-4

Sigmapharm’s first ANDA, filed in August 2013, had a disintegration specification of “not more than 5 minutes”—*Specification 1*. (PTX 525 at 9). In August 2015, the FDA issued a Complete Response, rejecting Specification 1 because the disintegration time was not “within seconds” as required by the Reference Listed Drug. (PTX 414 at 2). Because disintegration times directly implicated the issue of infringement, Forest sought emergency relief from Judge Robinson’s scheduling order “to avoid prejudice to Forest and a waste of resources by the Court.” (D.I. 419-1, Ex. A at 1).

On January 29, 2016, Judge Robinson issued an order, stating:

[F]or this case to go forward with some semblance of certainty, Sigmapharm must provide a declaration from one of its executives (binding Sigmapharm) stating that Sigmapharm will not reformulate its product and that Sigmapharm risks the costs of litigation if it does.

(*Id.*).

In response, Sigmapharm submitted a declaration from its CEO, Spiridon Spireas, Ph.D. stating that it will not “reformulate its ANDA products.” (D.I. 157-1). There was some discussion

at a subsequent status conference as to what the term “reformulate” would cover. (D.I. 419-1, Ex. B at 7:7-11:25). Judge Robinson made clear that any definition of reformulation created by Sigmapharm was not binding on her “so that if there are changes that hold up the case that in my mind constitute a reformulation, then I am saying that Sigmapharm is at risk for whatever costs that entailed.” (*Id.* at 10:15-21). Sigmapharm acknowledged Judge Robinson’s pronouncement and noted that it was only trying to exclude from the binding declaration “some small change that has nothing to do with disintegration.” (*Id.* at 11:17-25).

One month later, in February of 2016, Sigmapharm responded to the FDA’s rejection of Specification 1 by amending its disintegration specification to “not more than 75 seconds”—***Specification 2***.¹ (PTX 416 at 1, 13). Based on Specification 2, Forest prepared and served its opening expert reports, which included testing of lots PD 54:33 and 54:34. (*See* D.I. 409 at 11).

In May 2016, three months before trial was scheduled to start before Judge Robinson, Sigmapharm again amended its disintegration specification from “not more than 75 seconds” to “35 to 75 seconds”—***Specification 3***. (PTX 632 at 2). Forest again sought relief from Judge Robinson, asserting that if the FDA accepted Sigmapharm’s Specification 3, Forest would need additional fact and expert discovery. (D.I. 419-1, Ex. C). Sigmapharm took the position that no further discovery was needed. (*Id.*). According to Sigmapharm, “It is impossible for Forest to prove literal infringement because the specification precludes it.” (*Id.*). Judge Robinson was understandably troubled by Sigmapharm’s position that “everything that that happened before this is not relevant anymore, because you changed your label on your specification.” (D.I. 419-1, Ex. D at 28:15-18). In reference to Sigmapharm’s tactics, she noted that “maybe you’ve wasted a lot

¹ Although Sigmapharm had already provided a binding declaration to not reformulate its drug product, this amendment would have been expected, because Sigmapharm had not yet responded to the FDA’s rejection of Specification 1.

of time here and a lot of money.” (*Id.* at 29:23-24). In order to give Forest time to take additional discovery regarding Sigmapharm’s Specification 3, the trial date for all defendants was moved from August 2016 to October 2016. (D.I. 419-1, Ex. E at 5-6, 9:9-12).

In September 2016, the FDA rejected Sigmapharm’s Specification 3, reiterating its recommendation that Sigmapharm reformulate its drug product so that it demonstrated “a disintegration time that is in-line with the labeling requirement of ‘within seconds.’” (D.I. 384-1, Ex. 1 at ¶ 32; PTX 629 at 2). With trial set to commence in less than a month, Forest requested that any infringement issues as to Sigmapharm be stayed in order “to avoid prejudice to Forest and waste of the Court’s and Forest’s resources trying infringement of a product the FDA has twice not approved.” (D.I. 419-1, Ex. G). On October 13, 2016, Judge Robinson granted Forest’s request and trial on infringement as to Sigmapharm was stayed. (*Id.*). Meanwhile, Judge Robinson proceeded to trial in October 2016 on infringement as to the remaining defendants and validity as to all defendants. (*Id.*).

In response to the FDA’s September 2016 Complete Response, Sigmapharm again amended its disintegration specification in March 2017—**Specification 4**. (D.I. 384-1, Ex. 1 at ¶ 33). Sigmapharm changed the single disintegration test to two separate tests and lowered the upper time limit to under a minute. (PTX 630 at 15). Thus, the “35 seconds to 75 seconds” became:

- (1) at 30 seconds “fail” USP <701> (the “30-Second Test”), and
- (2) at 55 seconds “pass” USP <701> (the “55-Second Test”).

(*Id.*).

On July 25, 2017, having been designated as a visiting judge to assist with the Delaware Court’s docket, I was assigned this case. I rejected Sigmapharm’s motion to lift the stay in November 2017, because there was not enough certainty as to whether there would be further changes to Sigmapharm’s specification. (D.I. 341; D.I. 349; D.I. 351). But in January of 2018, I

granted a renewed motion to lift the stay after Sigmapharm received correspondence from the FDA classifying any remaining deficiencies in its ANDA as “minor.” (D.I. 353; D.I. 358). I also granted Forest’s request for additional fact discovery and supplemental expert reports on Specification 4, and the parties proceeded to trial before me in June 2018. (D.I. 356).

C. The Infringement Trial

At trial, Forest asserted that Sigmapharm infringed claims 1-2, 4-6, and 9-10 of the ’476 patent. (D.I. 384-1, Ex. 4). The parties agreed that Sigmapharm’s infringement of claims 2, 5, and 6 rose and fell with infringement of claim 1. (D.I. 362 at ¶ 3). The parties further agreed that infringement of claims 4, 9, and 10 would be resolved by applying to Sigmapharm any findings of infringement or non-infringement made against two other defendants in the consolidated case.² (*Id.* at ¶ 4). Given these agreements, the sole issue before me at the infringement trial was whether Sigmapharm infringed claim 1 of the ’476 patent either literally or under the doctrine of equivalents. (*Id.* at ¶ 3).

D. The Trial Opinion

On November 16, 2018, I issued a post-trial opinion finding that Sigmapharm literally infringed claim 1 of the ’476 patent. (D.I. 409). Because I found that Forest proved literal infringement, I did not decide the issue of infringement under the doctrine of equivalents. (*Id.* at 24). A finding of literal infringement depended on one issue: did Sigmapharm’s product “disintegrate within 30 seconds in water at 37° C.” (*Id.*). I found that it did. My finding was primarily premised upon the testimony of Forest’s expert, Dr. Adam Myers, who, based upon testing consistent with USP <701>, opined that Sigmapharm’s Specification 4 infringed Claim 1.

² The two other defendants are Breckenridge Pharmaceutical, Inc. (“Breckenridge”) and Alembic Pharmaceuticals Ltd., Alembic Global Holding S.A., and Alembic Pharmaceuticals, Inc. (collectively, “Alembic”).

Sigmapharm took the position that the two disintegration tests in Specification 4—the 30-Second Test and the 55-Second Test—precluded infringement. (*Id.* at 25-26). Sigmapharm equated “failing” USP <701> with proof that a batch of tablets would not disintegrate within 30 seconds. I rejected this approach as not consistent with the “words of the claim(s).” (*Id.* at 26). I found that a “fail” result would unreliably allow too many tablets to disintegrate within 30 seconds to conclusively show that a batch would not disintegrate within that time. (*Id.*). Specifically, up to 3/6 tablets on stage 1 and up to 15/18 tablets on stage 2 could disintegrate within 30 seconds and fail USP <701>. (*Id.*). But, experts on both sides opined that no more than 0/6 tablets on stage 1 and 2/18 tablets on stage 2 should disintegrate within 30 seconds in order to conclude that the batch would not disintegrate within 30 seconds. (*Id.*). And the experts also agreed that a hard core had to remain for 6/6 tablets on stage 1 and 16/18 or 17/18 tablets on stage 2 in order for the USP <701> test to be conclusive. (*Id.*).

E. Specification 5

The order accompanying the November 16, 2018 Trial Opinion stated that “[t]he parties shall submit an agreed upon form of final judgment to this effect.” (D.I. 410). Instead of submitting a proposed form of final judgment, Sigmapharm amended its ANDA by adopting **Specification 5**, and filed a motion pursuant to Fed. R. Civ. P. 60(b) asking me to change my infringement finding to non-infringement and enter final judgment in its favor. (D.I. 411, Ex. A at 21). According to Sigmapharm, Specification 5 changed the acceptance criteria under Sigmapharm’s 30-Second Test such that a batch of its tablets would not disintegrate within 30 seconds. (*Id.*). In other words, Sigmapharm now posits no more than 0/6 tablets will disintegrate within 30 seconds on stage 1 and 2/18 tablets on stage 2. (*Id.*). According to Sigmapharm, the FDA approved Specification 5 by default.

II. DISCUSSION

A. Relief from Judgment Under Rule 60(b)

Sigmapharm seeks relief from judgment pursuant to Fed. R. Civ. P. 60(b)(2), 60(b)(5), and 60(b)(6). (D.I. 411 at 9).

1. Rule 60(b)(2)

Rule 60(b)(2) allows a court to grant relief from a final judgment when there is “newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b).” Fed. R. Civ. P. 60(b)(2). Under Rule 60(b)(2), “newly discovered evidence is evidence of facts in existence at the time of trial of which the aggrieved party was excusably ignorant.” *Colyer v. Consol. Rail Corp.*, 114 F. App’x 473, 481 (3d Cir. 2004) (alterations omitted) (emphasis in original) (quoting *Bohus v. Beloff*, 950 F.2d 919, 930 (3d Cir. 1991).

Here, Specification 5 was not in existence at the time of trial. Instead, Sigmapharm created Specification 5 after trial, in response to my finding of infringement. A fact arising after trial “does not meet the definition of newly discovered evidence.” *See Colyer*, 114 F. App’x at 481. Because Specification 5 does not qualify as “newly discovered evidence,” it is not grounds to grant relief under Rule 60(b)(2).

2. Rule 60(b)(5)

Under Rule 60(b)(5), the court may grant relief from a final judgment when “applying it prospectively is no longer equitable.” Fed. R. Civ. P. 60(b)(5). Rule 60(b)(5) “provides a means by which a party can ask a court to modify or vacate a judgment or order if ‘a significant change either in factual conditions or in law’ renders continued enforcement ‘detrimental to the public interest.’” *Horne*, 557 U.S. at 447 (quoting *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367,

384 (1992)). However, “Rule 60(b)(5) may not be used to challenge the legal conclusions on which a prior judgment or order rests.” *Horne v. Flores*, 557 U.S. 433, 447 (2009); *see also Allergan, Inc. v. Sandoz Inc.*, 2013 WL 6253669, at *2 (E.D. Tex. Dec. 3, 2013) (“[A] party may not use a Rule 60(b) motion as an occasion to relitigate its case.” (quoting *United States v. Davison*, 509 F. App’x 330, 332 (5th Cir. 2013))). The party seeking relief under Rule 60(b)(5) “bears the burden of establishing that changed circumstances warrant relief.” *Horne*, 557 U.S. at 447.

Importantly, Rule 60(b)(5) “empowers a court to modify a judgment only if it is ‘prospective,’ or executory.” *United States v. Alsol Corp.*, 620 F. App’x 133, 135 (3d Cir. 2015) (emphasis added). In other words, Rule 60(b)(5) only “provides for relief from injunction or consent decrees.” *Gillespie v. Janey*, 527 F. App’x 120, 121 (3d Cir. 2013). Here, Sigmapharm is not seeking modification to an injunction or consent decree, but a change to legal conclusions. Accordingly, Rule 60(b)(5) is not the proper grounds to grant the relief Sigmapharm seeks.

The cases on which Sigmapharm relies for its changed circumstances argument are inapposite. *Allergan, Inc. v. Sandoz Inc.* addressed whether a party was entitled to modification of an injunction. *See* 2013 WL 6253669, at *2. *Allergan* applied the law set forth by the United States Supreme Court in *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367 (1992). In *Rufo*, the Supreme Court stated that a court may modify “the terms of an injunctive decree if the circumstances, whether of law or fact, obtaining at the time of its issuance have changed, or new ones have since arisen.” *See* 502 U.S. at 380 (emphasis added) (quoting *Sys. Fed. No. 91, Ry. Emp. Dept., AFL-CIO v. Wright*, 364 U.S. 642, 647 (U.S. 1961)). As noted previously, the issue before me does not implicate injunctive relief.

3. Rule 60(b)(6)

Rule 60(b)(6) is a catchall provision that allows a court to relieve a party from the effects of an order for “any other reason justifying relief from the operation of the judgment.” Fed. R. Civ. P. 60(b)(6). Courts have “consistently held that the Rule 60(b)(6) ground for relief from judgment provides for extraordinary relief and may only be invoked upon a showing of exceptional circumstances.” *In re Fine Paper Antitrust Litig.*, 840 F.2d 188 (3d Cir. 1988) (quotation omitted). The party seeking relief has the burden of showing that absent such relief, an “extreme” and “unexpected” hardship will result. *Budget Blinds, Inc. v. White*, 536 F.3d 244, 255 (3d Cir. 2008). An unexpected hardship “rarely exist[s] when a party seeks relief from a judgment that resulted from the party’s deliberate choices.” *Id.*

Sigmapharm has not demonstrated an extreme and unexpected hardship warranting relief. Sigmapharm suggests that my finding (that failure of USP <701> is not conclusive proof of non-infringement) was unexpected and has, therefore, created an extreme hardship. According to Sigmapharm, it had every reason to expect that failing USP <701> was conclusive proof of non-infringement due to: (i) the Judge Robinson’s prior claim construction and, (ii) a purported agreement between the parties. (D.I. 411 at 5). For the reasons explained below, Sigmapharm’s expectation was unreasonable and unilateral, and any trial strategy based on that expectation was Sigmapharm’s miscalculation.

a. Claim Construction

On January 29, 2016, Judge Robinson issued a claim construction opinion. (D.I. 133). At the time, the parties did not dispute, and Judge Robinson did not construe, any terms from claim 1 of the ’476 patent. (*Id.*). Judge Robinson did, however, construe the following phrase in claim 9 of the ’476 patent: “A solid pharmaceutical composition which rapidly disintegrates.” (*Id.* at ¶ 3).

Judge Robinson found that the '476 patent expressly provided a definition of the term “rapid disintegration” and adopted that definition for the disputed phrase in claim 9. (*Id.*) The express definition for “rapid disintegration” is “the pharmaceutical composition is disintegrated within 30 seconds in water at 37° C., and preferably within 10 seconds, as measured according to the procedure described in Remington’s Pharmaceutical Sciences, 18th Edition (Ed. A. R. Genaro) 1990 pp 1640-1641; see also US Pharmacopeia, Chapter <701 >.” (*Id.*)

For several reasons, it was unreasonable for Sigmapharm to expect, based on Judge Robinson’s claim construction, that “failing” USP <701> was conclusive proof that its generic product would not literally infringe claim 1. First, Judge Robinson issued a construction of claim 9, not claim 1, and the disputed terms in claim 9 and claim 1 are not the same. Claim 9 calls for “[a] solid pharmaceutical composition which rapidly disintegrates,” whereas claim 1 calls for a solid pharmaceutical composition that “disintegrates within 30 seconds in water at 37° C.” Thus, Sigmapharm unreasonably assumed that the construction of a different term in a different claim applied to claim 1.

Second, there was nothing in Judge Robinson’s construction of claim 9 that declared or suggested that failure of USP <701> means no literal infringement. The construction only addressed how a POSA can determine whether tablets *will* disintegrate within 30 seconds. Judge Robinson said nothing about how to determine whether tablets *will not* disintegrate within 30 seconds. In addition, the words “pass” or “fail” appear nowhere in the claim construction order. Thus, Sigmapharm assumed, at its own risk, that failure of USP <701> showed that the tablets will not disintegrate within 30 seconds.

b. The Parties “Agreement”

Sigmapharm also presses that, “the parties agreed that ... ‘failing’ USP <701> at 30 seconds was not literal infringement.” (*See* D.I. 411 at 10). The only cited basis for Sigmapharm’s assertion is the following exchange during the cross-examination of Forest’s expert, Dr. Elizabeth Illum, at trial:

Q. Okay. And if you fail the USP at 30 seconds, you don’t literally infringe claim one, right?

A. You don’t literally infringe, no.

(D.I. 389 at 27:20-22). For several reasons, this testimony is not sufficient grounds for Sigmapharm to claim that their “failing USP <701>” theory was stipulated to by Forest.

First, Dr. Illum’s testimony must be read in context. It was a single question and answer during a cross-examination with no foundation or follow-up. In addition, Dr. Illum testified during the same cross-examination that the meaning of “pass” and “fail” was “very confusing” because Sigmapharm inverted the terms. (D.I. 389 at 33:24-24:10). Indeed, on another question, she admitted to using “pass” when she meant “fail.” (*Id.*).

Second, and more important, Dr. Illum provided extensive testimony that USP <701> is a test designed to determine whether a batch of tablets will disintegrate below a given time limit, and explained that it is not a test designed to determine whether the batch of tablets will disintegrate above a certain time limit. (D.I. 388 at 61:5-62:15). When asked to design such a test, Dr. Illum testified that she would require 0/6 tablets on stage one or 15/18 tablets on stage 2 to not disintegrate within the given time limit. (*Id.* at 63:8-18). Dr. Illum further testified that Sigmapharm’s proposed test—“failing” USP <701>—was insufficient, because it would assume that an entire batch of tablets would disintegrate within a certain time if only 17% of the sample tablets disintegrated within that time. (*Id.* at 63:2-7). This is the same position Dr. Illum took

during discovery. (D.I. 419-1, Ex. J at ¶ 30). Therefore, Sigmapharm was on notice that Forest did not agree that failing USP <701> was proof of no literal infringement.

Third, even if Dr. Illum agreed with Sigmapharm that failing USP <701> was conclusive proof of no literal infringement, “nothing in the rules requires a fact finder to accept” an expert’s conclusion as to the ultimate issue in a case. *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997). As a factfinder, I was free “to accept or reject the testimony of each witness in whole or in part.” *Finjan, Inc. v. Symantec Corp.*, 2013 WL 5302560, at *28 (D. Del. Sept. 19, 2013). Thus, Sigmapharm should not have expected me to adopt without question one answer that failing USP <701> could be proof of no literal infringement. And Sigmapharm has not cited any precedent that an expert’s answer (taken out of context) is somehow binding on a party.

Finally, other events at trial underscore the fact that Sigmapharm unilaterally adopted its “failing USP <701>” theory. During the cross-examination of Forest’s expert, Dr. Adam Myers, Sigmapharm represented that Judge Robinson construed the disintegration limitation of claim 1 and asked Dr. Myers to agree that this construction was the test for literal infringement of claim 1. (D.I. 387 at 63:22-64:17). Forest objected on the grounds that Judge Robinson construed claim 9, but not claim 1. (*Id.* at 64:18-69:4). Unable to determine in the crucible of trial what had transpired earlier in the case with Judge Robinson, I asked the parties to meet and confer over the issue. Ultimately, the parties stated on the record that they “were not able to reach agreement” on “the standard of proof for literal infringement of claim 1.” (D.I. 387 at 69:10-13).

For all of the foregoing reasons, Sigmapharm has not demonstrated “exceptional circumstances” warranting relief under Fed. R. Civ. P. 60(b)(6). Sigmapharm’s Motion to Enter Judgment in its Favor is denied. (D.I. 411).

B. Federal Circuit Case Law on Post-Trial Amendments

I am mindful of the fact that the Federal Circuit has in certain instances approved a district court's finding of non-infringement based on an ANDA amended after trial. *See, e.g., Ferring B.V. v. Watson Laboratories, Inc.*, 764 F.3d 1382 (Fed. Cir. 2014). In *Ferring*, the issue of infringement depended entirely on dissolution rates. *Id.* at 1385. The patent holder "conceded, and the district court found, that Apotex's actual product, based on its dissolution sample data, did not infringe the patents-in-suit." *Id.* at 1386. In addition, "Ferring's expert testified that none of the tablets produced by Apotex in discovery was infringing." *Id.* at 1388. Nevertheless, the district court concluded that Apotex's original ANDA infringed the patents-in-suit, because the ANDA was silent with respect to the percentage weight of the active ingredient dissolved by 45 minutes and, therefore, permitted Apotex to sell an infringing product. *Id.*

At trial, Apotex agreed to amend its ANDA to include a restriction that not less than 75 percent by weight of the active ingredient was released at 45 minutes, which the district court agreed would have prevented Apotex from selling any infringing product. *Id.* at 1386. After trial, Apotex amended its ANDA as agreed, and based on the amended ANDA, the district court dismissed Ferring's claims as moot. *Id.* at 1367. The Federal Circuit affirmed the district court's ruling, stating:

A district court may reconsider its own finding of infringement in light of an amended ANDA or other information.... We do not suggest that a district court must always consider any ANDA amendment. Allowing an amendment is within the discretion of the district court, guided by principles of fairness and prejudice to the patent-holder.

Id. at 1391. (emphasis added)

Notably, the Federal Circuit found no prejudice by Apotex's late amendment. As the court explained, "even at trial the district court made clear that it was inclined to allow an amendment by Apotex clarifying the dissolution rate of its product, and the district court judge discussed the

language of the amendment on the record.” *Id.* at 1391. In addition, Ferring never requested that the district court reopen the record to address infringement by the amended ANDA. *Id.* at 1391-92.

Ferring is entirely distinguishable from the facts before me on several grounds. First, unlike in *Ferring*, my finding of infringement was not based solely on the ANDA, but also on actual testing of Sigmapharm’s generic product. Whereas Ferring’s experts opined that testing of Apotex’s product showed no infringement, here Forest’s experts credibly opined that the testing of Sigmapharm’s product did establish actual infringement. And whereas Ferring conceded that Apotex’s actual product did not infringe, Forest rigorously contested this fact and proved that Sigmapharm’s actual product did infringe.

Second, there was no discussion at the trial before me suggesting that Sigmapharm would or should amend its ANDA to moot the issue of infringement. Indeed, the opposite is true, especially given Judge Robinson’s Order that Sigmapharm provide a binding declaration that it would not reformulate its drug product. (D.I. 419-1, Ex. A at 1). When that proved insufficient to prevent several subsequent amendments, Judge Robinson severed and stayed Sigmapharm’s infringement issues from the consolidated case. The purpose of the stay was to prevent a waste of judicial resources and provide certainty on the issues of infringement to be tested at trial. I lifted the stay in part, based upon Sigmapharm’s implicit assurances that there would be no further changes to disintegration specification.

Third, the *Ferring* court found no prejudice because, among other reasons, Ferring never requested that the district court reopen the record to address infringement by the amended ANDA. *Ferring*, 764 F.3d at 1391-92. But here, every time Sigmapharm has amended its disintegration

specification, Forest has understandably sought discovery to test whether the new disintegration specification precluded a finding of infringement.

It also appears that all of the patentee's infringement theories in *Ferring* were mooted by the amended ANDA. That is not the case here. According to Forest, Sigmapharm's product infringed the '476 patent both literally and under the doctrine of equivalents. Because I found literal infringement, I never addressed infringement under the doctrine of equivalents. Thus, my rulings do not, as Sigmapharm claims, "conclusively establishe[] the requirements for non-infringement of Claim 1 of the '476 patent." (D.I. 411 at 1). Even if Sigmapharm's Specification 5 precludes literal infringement, which I have not yet determined, the issue of infringement under the doctrine of equivalents remains unresolved.

I also disagree with Sigmapharm that infringement under the doctrine of equivalents can be determined based upon the existing record. According to Sigmapharm "[n]either the issue of infringement under the doctrine of equivalents nor prosecution history estoppel is affected by the November 2018 Amendment and these issues stand ready for disposition at the Court's discretion." (D.I. 411 at 20). Even if the parties do not need to supplement the record in order to litigate issues related to the doctrine of equivalents, it is neither fair to Forest nor an efficient use of judicial resources for me to guess as to how the parties will modify their arguments based on the amendments made in Specification 5. The parties should perform that labor in the first instance.

Finally, Sigmapharm argues that the principles of fairness discussed in *Ferring* weigh in its favor. Specifically, Sigmapharm argues that "The Court's definitive finding of the way to preclude infringement of Claim 1 was not previously available to Sigmapharm and, in fairness, Sigmapharm should be given an opportunity to update its specifications in light of the Court's guidance." (D.I. 411 at 16). Federal courts, however, are "not in the business of issuing advisory

opinions.” *In re Horn*, 185 F. App’x 199, 202 (3d Cir. 2006). Thus, my November 16, 2018 opinion was not “guidance,” nor was it green lighting Sigmapharm to engage in a do-over, after they learned of the weaknesses in its legal theory. This is inconsistent with notions of securing a “just, speedy, and inexpensive” determination of this action. *See* Fed. R. Civ. P. 1.

C. Forest’s Motion to Enter Final Judgment

Although I decline to enter a final judgment in Sigmapharm’s favor based on Specification 5, I question the value of entering a final judgment in Forest’s favor based on Specification 4. Specification 4 is no longer operative. In addition, Sigmapharm asserts that, due to the changes made by Specification 5, “[t]he batches tested by [Forest], some of which were found to infringe, are no longer representative, in terms of disintegration characteristics, of the products that Sigmapharm will manufacture and market.” (D.I. 423 at 5). Nothing precludes me from disregarding Specification 5 and entering final judgment as to Specification 4 based on the findings set forth in the November 18, 2018 trial opinion. *See, e.g., Allergan*, 2013 WL 6253669, at *3 (denying motion to amend judgment under Rule 60(b) based on an ANDA amended after trial). Nevertheless, if Sigmapharm wants the opportunity to prove that Specification 5 does not infringe the ’476 patent, either literally or under the doctrine of equivalents, I am willing to provide that opportunity.

Because I am denying Sigmapharm’s motion to amend the judgment in its favor, Sigmapharm has two options: (1) have a final judgment entered based on the November 16, 2018 opinion addressing Specification 4 and appeal that judgment to the United States Court of Appeals for the Federal Circuit, or (2) request that I reinstate the discovery and litigation process with respect to Specification 5. During oral argument on the pending motions, Sigmapharm did not express a preference for either option, but needs to do so now. (*See* D.I. 427 at 44:20-45:9).

Accordingly, I will deny without prejudice Forest's Motion to Enter Final Judgment. (D.I. 413). The parties shall submit, after a meet and confer, a joint status report that: (a) notifies me whether I should enter final judgment on Specification 4 or whether the parties will proceed to litigate infringement under Specification 5, and (b) attaches either (i) a proposed final judgment for Specification 4 or (ii) a proposed scheduling order governing litigation of Specification 5.

III. CONCLUSION

For the foregoing reasons, the parties' motions to enter a final judgment (D.I. 411; D.I. 413) are DENIED (Forest's, without prejudice). An appropriate order will be entered.